



#14
N.L.H.
3-29-03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of)
LABERGERIE et al.)
Serial No.: 09/735,092) Art Unit: 1761
Filed: 12/12/2000) Examiner: L. WONG

FOR: DEXTROSE HYDRATE IN POWDER FORM AND A PROCESS FOR
THE PREPARATION THEREOF

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DECLARATION UNDER RULE 132

To Honorable Commissioner of Patents and Trademarks
Washington, D.C.

Sir:

I, Philippe LEFEVRE, of 3600, rue de Merville,
59600 HAVERSKERQUE, France, do solemnly declare:

THAT I am a graduate of the "ECOLE NATIONALE
SUPERIEURE DE CHIMIE" of Lille 59000 - France;

THAT I have been working as chemical engineer since
February 28th, 1985 and that I now hold the position of
manager of the Pharmaceutical and Cosmetic Applications
Department at ROQUETTE FRERES;

THAT I am a named inventor on the present patent
application n° 09/735,092, I am fully familiar therewith
and I am competent to give an opinion regarding the
techniques and subject matter thereof;

THAT I have read and understood the Office action
mailed on December 11, 2002 in connection with the patent
application in reference;

THAT I have read and understood the document WO 94/28181 to Chase et al.;

THAT in support of my declaration filed on September 30, 2002, I performed a comparative test between the dextrose in powder form of Chase et al. and the dextrose hydrate in powder form of the invention in order to evidence that the compressibility of the dextrose in powder form of Chase et al. have a compressibility of less than 70 N whereas the dextrose hydrates in powder form of the invention have a compressibility at least equal to 70 N;

THAT I measured said compressibility using test A described in my patent application U.S. No. 09/735,092 for tablets having a density ranging from 1,195 to 1,445 g/ml,

THAT I used samples of dextrose in powder form prepared according to the process of Chase et al..

THAT I used samples of dextrose hydrate in powder form of the invention which have been prepared according to the invention and which have the claimed characteristics, namely a dextrose content at least equal to 99 %, an α crystalline form content at least equal to 98 % and a water content of 7,6 %,

THAT I present the results of compressibility obtained from said comparative test on a graphic enclosed to my declaration,

THAT I conclude from my comparative test and resulting graphic that the dextrose hydrate in powder form of the invention has a compressibility of at least 70 N, whereas the dextrose in powder form of Chase et al. has a compressibility lower than 60 N.

I, the undersigned, declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and, further, that these statements

were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001, of Title 18, of the United States Code, and that such wilful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 07.03.03 .

Philippe LEFEVRE

A handwritten signature in black ink, appearing to be 'PL' with a stylized flourish underneath.



DEXTROSE COMPRESSIBILITY

